

## **REMARKS**

Claims 1, 3, 4 and 7 are pending and under active consideration. Applicants respectfully point out that on page one of the Office Action Claim 3 is listed as both allowed and rejected. Applicants have responded to the rejection of Claim 3 below.

Claim 3 has been amended to clarify the invention as described in the specification as originally filed. Claim 3 has been amended to recite the phrase "encoded by a genome comprising." Support for the amendment is found at page 7, lines 1 and 2; and page 10, lines 35 and 36. The amendment is fully supported by the specification as originally filed, as indicated hereinbelow. No new matter has been added.

Applicants respectfully request that the amendments and remarks made herein be entered into the record of the instant application.

### **REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH FOR LACK OF WRITTEN DESCRIPTION**

Claim 3 has been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was allegedly not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Examiner contends that the sequences according to SEQ ID NO:1-7 correspond to only a portion of a retroviral genome and comprise about 100 base pairs, which is not sufficient to describe the full length genome of the genus of PSC associated retroviruses encompassed by the instant claim. Furthermore, the Office Action states that further experimentation would be required by one skilled in the art to described every element of the PSC associated retroviruses encompassed by the claim, and that the claim reads on a retrovirus that comprises an exogenous nucleotide sequence comprising SEQ ID NO:1-7<sup>1</sup>.

The legal standard for the written description requirement of 35 U.S.C. § 112, first paragraph, requires that an applicant "must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555; 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). The Federal Circuit has also clearly indicated that, "[a] specification may, within the meaning

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<sup>1</sup> Page four of the Office Action dated April 7, 2003 recites "claim 1 broadly reads on a retrovirus comprising..." Applicants believe the claim number recited is in error, since claim 1 does not recite a retrovirus, but rather specific sequences thereof.

of 35 U.S.C. § 112, first paragraph, contain a written description of a broadly claimed invention without describing all species that the claim encompasses." *Utter v. Hiraga*, 845 F.2d 993 (Fed. Cir. 1988).

With respect to the contention that the claim reads on a retrovirus that comprises an exogenous nucleotide sequence comprising SEQ ID NO:1-7, Applicants respectfully disagree. Though applicants disagree with the rejection, in the interest of advancing prosecution, without acquiescing to the Examiner's rejection, applicants have amended claim 3 to recite "encoded by a genome comprising." Thus, the composition of claim 3, as amended, does not encompass a retrovirus that comprises an exogenous nucleotide sequence comprising SEQ ID NO:1-7.

Furthermore, Applicants submit the application as filed contains sufficient written description support for the claimed composition. Applicants were clearly in possession of several compositions comprising an isolated PSC associated retrovirus, wherein the retrovirus comprises a genome comprising a nucleotide sequence comprising SEQ. ID. NOs. 1, 2, 3, 4, 5, 6, 7, or the compliment thereof. Since the sequences of the invention are unique to PSC associated retrovirus, Applicants were able to isolate compositions comprising PSC associated retrovirus from tissues and cells. (For example, at page 33, lines 9 through 22 of the specification, a description of how virus was isolated from bile samples of patients having PSC is disclosed). Novel PSC associated retroviral nucleotide sequences, corresponding to SEQ. ID. NOs: 1-3, were then identified in the isolated viral compositions derived from the bile, see the specification at page 37, Table 3, lines 10-23. Furthermore, isolated viral compositions derived from serum, liver, and colon were prepared and tested for the presence of PSC associated retrovirus using the novel PSC associated retroviral nucleotide sequences, i.e., SEQ ID NO:1-7 or compliments thereof, see the specification at page 39, lines 8-9. The descriptions of isolated viral sample that tested positive shows that applicants were in possession of compositions comprising an isolated PSC associated retrovirus comprising a nucleotide sequence comprising SEQ. ID. NOs: 1, 2, 3, 4, 5, 6, 7, or the compliment thereof. Thus, applicants were clearly in possession of a composition comprising an isolated PSC associated retrovirus, wherein the retrovirus comprises a nucleotide sequence comprising SEQ. ID. NOs: 1, 2, 3, 4, 5, 6, 7, or the compliment thereof. In accord with case law, applicants have described several species of the claimed composition and have met the established written description requirements.

As reasoned above, applicants have not only described the compositions, but have reduced the invention to practice, without the full genome sequence, using the novel sequences specific to PSC associated retroviruses to identify PSC, associated retrovirus and techniques for isolating virus from a patient's cells and tissues. Contrary to the Examiner's position, Applicants demonstrated that they are in possession of the claimed compositions comprising PSC associated retroviruses.

The written description requirement of 35 U.S.C. § 112, first paragraph, requires disclosure of a reduction to practice of the invention, or the complete structure of a species within the claim. In the present instance applicants have reduced the invention to practice and thus meet the written description requirements. However, assuming *arguendo*, applicants had not reduced the claimed composition to practice, applicants still meet the criteria for describing the structure of a species. The written description requirement also requires that where a complete structure is not disclosed, disclosure of other relevant characteristic, such as structural or other physical and/or chemical properties, or functional characteristics in combination with a correlation between structural and functional characteristics, is sufficient evidence that the applicants were in possession of the claimed invention as of the filing date of the application. The criteria for determining sufficiency of written description set forth in Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 1, "Written Description" Requirement ("the Guidelines") (published in the January 5, 2001 Federal Register at Volume 66, Number 4). According to the Guidelines, for each claimed genus, the test requires determination of whether there is sufficient description of,

" . . . a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, functional characteristics when coupled with known or disclosed correlation between function and structure, or some combination of such identifying characteristics sufficient to show the applicant was in possession of the claimed genus." *Id.* at page 1106, column 3, lines 12-29.

Where the specification discloses any relevant identifying characteristics, i.e., physical, chemical and/or functional characteristics, sufficient to allow a skilled artisan to recognize the applicant was in possession of the claimed invention, a rejection for lack of written description under Section 112, first paragraph, is misplaced.

In the instant action, the Examiner has applied the genus test, and contends that the specification does not disclose the entire genomes of PSC associated retroviruses or even a species of that genus. Applicants assert that the specification describes relevant identifying structural characteristics, i.e., SEQ. ID. NO: 1-7 or compliments thereof, and that the skilled artisan would know that the applicants were in possession of the claimed composition. Moreover, contrary to the Office Action, further experimentation to describe every element of the PSC associated retrovirus of the claimed composition would not be necessary, since according to the written description guidelines, relevant identifying structural characteristics are sufficient to meet the written description requirement.

The description is deemed sufficient if it demonstrates to the skilled artisan that the applicant was in possession of the necessary common attributes of the members of the genus. *Eli Lilly*, 119 F.3d at 1568, 43 U.S.P.Q.2d at 1405. In the present instance, the invention of the rejected claims is described by unique structural characteristics common to the genus – containing a specific, defined nucleotide sequence, i.e., SEQ. ID. NOs. 1, 2, 3, 4, 5, 6, 7, or the compliment thereof. Applicants have demonstrated that these PSC retroviral associated sequences are novel and not homologous to other known retroviral sequences, see page 37, lines 6-8. Armed with the disclosure that the claimed polynucleotides must contain that particular nucleotide sequence, the skilled artisan should certainly be able to identify and envision members of the genus. Applicants submit that, since the recited identifying characteristic, i.e., containing a recited nucleotide sequence, is sufficient to permit the skilled artisan to envision and identify members of the genus, no other structural or functional characteristics are required. Thus, contrary to the assertions made in the Office Action, disclosure of the nucleotide sequences coupled with actual reduction to practice provides sufficient written description support for compositions comprising PSC associated retrovirus having the particular PSC sequence.

Applicants respectfully submit that the rejected claim does have written description support in the specification and request that the rejection be withdrawn.

## CONCLUSION

Applicants respectfully request that the present amendments and remarks be entered and made of record in the instant application. Applicants estimate that the amendments and remarks made herein now place the pending claims in condition for allowance. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

It is believed that no fee is required for filing this Reply. In the event a fee is required, please charge the required fee to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

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Enclosures